

IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION

SEAGEN INC., )  
Plaintiff, ) CASE NO. 2:20-cv-00337-JRG  
v. ) JURY TRIAL DEMANDED  
DAIICHI SANKYO CO., LTD., )  
Defendant. )  
)  
)

**DEFENDANT DAIICHI SANKYO COMPANY,  
LIMITED'S ANSWER TO PLAINTIFF'S COMPLAINT**

Defendant Daiichi Sankyo Company, Limited (“Daiichi Sankyo Japan”), by and through undersigned counsel, answers the Complaint<sup>1</sup> of Plaintiff Seagen Inc. (“Seagen”) as follows:

1. Daiichi Sankyo Japan denies each and every allegation in Paragraph 1.
2. Daiichi Sankyo Japan admits that Seagen attempts to describe antibody-drug conjugates, but Seagen’s description is very general, incomplete, and misleading. Daiichi Sankyo Japan further admits that Seagen attempts to allege that as of the date of Seagen’s Complaint that only nine antibody-drug conjugates have been approved by the FDA. However, it is not clear to which type of FDA approval Seagen’s Complaint refers, so Daiichi Sankyo Japan denies this allegation. Except as admitted, Daiichi Sankyo Japan denies each and every allegation in Paragraph 2.

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<sup>1</sup> Daiichi Sankyo Japan does not believe that this heading or any of the headings in Seagen’s Complaint require a response. If a response is required, Daiichi Sankyo Japan denies each and any allegations, express or implied, in such headings.

3. Daiichi Sankyo Japan admits that Seagen received a FDA approval in 2011 for the antibody-drug conjugate known as Adcetris®. Except as admitted, Daiichi Sankyo Japan denies each and every allegation in Paragraph 3.

4. Daiichi Sankyo Japan denies each and every allegation in Paragraph 4.

5. Daiichi Sankyo Japan lacks knowledge or information sufficient to form a belief as to the truth of what Seagen intends by its Complaint and denies that allegation on that basis. Daiichi Sankyo Japan denies each and every remaining allegation in Paragraph 5.

#### **THE PARTIES**

6. Daiichi Sankyo Japan admits that Seagen is a biotechnology company formerly known as Seattle Genetics, Inc. On information and belief, Daiichi Sankyo Japan further admits that Seagen is headquartered in Bothell, Washington, and is incorporated under the laws of Delaware. Except as admitted, Daiichi Sankyo Japan denies each and every allegation in Paragraph 6.

7. Daiichi Sankyo Japan admits that Daiichi Sankyo Company, Limited is a Japanese corporation with its principal place of business at 3-5-1, Nihonbashi, Honchō, Chūo-ku, Tokyo 103-8426, Japan.

#### **JURISDICTION AND VENUE**

8. Daiichi Sankyo Japan denies each and every allegation in Paragraph 8.

9. Daiichi Sankyo Japan denies each and every allegation in Paragraph 9.

10. Daiichi Sankyo Japan owns the registration for the Enhertu® trademark for DS-8201. Daiichi Sankyo Japan denies each and every remaining allegation in Paragraph 10.

11. Daiichi Sankyo Japan denies each and every allegation in Paragraph 11.

12. Daiichi Sankyo Japan denies each and every allegation in Paragraph 12.

13. Daiichi Sankyo Japan denies each and every allegation in Paragraph 13.

**PATENT-IN-SUIT – U.S. PATENT NO. 10,808,039**

14. Daiichi Sankyo Japan lacks knowledge or information sufficient to form a belief as to the truth of Seagen's alleged ownership of U.S. Patent No. 10,808,039 ("the '039 patent" or "the patent-in-suit") and whether Seagen has the sole right to enforce it, and denies that allegation on that basis. Daiichi Sankyo Japan denies each and every remaining allegation in Paragraph 14.

15. Daiichi Sankyo Japan admits that Seagen attempts to state what the '039 patent claims as well as a purported history of antibody-drug conjugate technology. Seagen's allegations, however, are incomplete, misleading, and unclear. Except as admitted, Daiichi Sankyo Japan denies each and every allegation in Paragraph 15.

16. Daiichi Sankyo Japan denies each and every allegation in Paragraph 16.

**ALLEGED INFRINGEMENT**

17. Daiichi Sankyo Japan denies each and every allegation in Paragraph 17.

18. Daiichi Sankyo Japan denies each and every allegation in Paragraph 18.

19. Daiichi Sankyo Japan denies each and every allegation in Paragraph 19.

20. Daiichi Sankyo Japan denies each and every allegation in Paragraph 20.

**COUNT I**

21. Daiichi Sankyo Japan repeats and realleges its answers and denials to the preceding Paragraphs as if fully set forth here.

22. Daiichi Sankyo Japan denies each and every allegation in Paragraph 22.

23. Daiichi Sankyo Japan denies each and every allegation in Paragraph 23.

24. Daiichi Sankyo Japan denies each and every allegation in Paragraph 24.

25. Daiichi Sankyo Japan denies each and every allegation in Paragraph 25.

26. Daiichi Sankyo Japan denies each and every allegation in Paragraph 26.
27. Daiichi Sankyo Japan denies each and every allegation in Paragraph 27.
28. Daiichi Sankyo Japan denies each and every allegation in Paragraph 28.
29. Daiichi Sankyo Japan denies each and every allegation in Paragraph 29.

**PRAYER FOR RELIEF**

30. Daiichi Sankyo Japan denies that Seagen is entitled to any relief from Daiichi Sankyo Japan or the Court, either as prayed for in the Complaint or otherwise. Daiichi Sankyo Japan has not infringed, either directly or indirectly, any valid and enforceable claim of the patent-in-suit, and Seagen is not entitled to any remedy or recovery. To the extent paragraphs A-F under Plaintiff's Prayer for Relief are interpreted to contain any factual allegations, Daiichi Sankyo Japan denies them.

**DEFENSES**

Daiichi Sankyo Japan asserts the following defenses. In doing so, Daiichi Sankyo Japan does not assume the burden of proof for matters for which Seagen bears the burden. Daiichi Sankyo Japan also reserves all rights to allege additional defenses that become known during the litigation.

**First Defense**  
**(Non-Infringement)**

Daiichi Sankyo Japan does not infringe, and has not infringed (directly, indirectly, literally or under the doctrine of equivalents) any valid and enforceable claim of the '039 patent.

**Second Defense**  
**(Invalidity)**

The claims of the '039 patent are invalid and/or unenforceable for failure to satisfy one or more of the patentability conditions set forth in Title 35 of the U.S. Code, including but not limited to 35 U.S.C. §§ 102 and 112.

**Third Defense**  
**(Prosecution Laches)**

The claims of the '039 patent are unenforceable and Seagen's claims for relief are barred by the equitable doctrine of prosecution laches due to Seagen's unreasonable and unexplained delay in the prosecution of the patent application resulting in the '039 patent.

**Fourth Defense**  
**(Estoppel, Waiver, and Unclean Hands)**

Seagen's claims for relief are barred, in whole or in part, by the equitable doctrines of estoppel, waiver and/or unclean hands.

**Fifth Defense**  
**(Prosecution History Estoppel)**

Seagen's infringement claims are barred by the doctrine of prosecution history estoppel based on statements, representations, and admissions made during the prosecution of the patent application resulting in the '039 patent.

**Sixth Defense**  
**(No Exceptional Case)**

Seagen pleaded no valid basis for finding an exceptional case under 35 U.S.C. § 285.

**Seventh Defense**  
**(Limitation of Damages)**

Seagen's claims for damages, costs, or attorneys' fee, if any, against Daiichi Sankyo Japan for alleged patent infringement is limited by 35 U.S.C. §§ 286 and/or 288.

**Eighth Defense**  
**(Safe Harbor)**

Daiichi Sankyo Japan's alleged activities with regard to Daiichi Sankyo Japan's "pipeline products" that Seagen mentions in its Complaint—U3-1402, DS-1062, DS-7300, and DS-6157, do not constitute infringement as a matter of law under 35 U.S.C. § 271(e)(1).

**RESERVATION OF RIGHTS**

Defendant reserves the right to assert any additional defenses, as they become known during the course of this action, or to the extent they are not otherwise deemed affirmative defenses by law.

**PRAYER FOR RELIEF**

WHEREFORE, Daiichi Sankyo Japan prays for judgment that:

- A. Seagen's Complaint against Daiichi Sankyo Japan be dismissed in its entirety with prejudice;
- B. Seagen is not entitled to any relief prayed for in its Complaint against Daiichi Sankyo Japan, or to any relief whatsoever;
- C. Daiichi Sankyo Japan has not infringed any valid and enforceable asserted claim of the '039 patent;
- D. Each asserted claim of the '039 patent is invalid and unenforceable;
- E. The claims of the '039 patent are unenforceable due to the equitable doctrine of prosecution laches;
- F. No damages or royalties are due or owing for any of the acts alleged by Seagen in its Complaint as to Daiichi Sankyo Japan;
- G. Daiichi Sankyo Japan be awarded its costs, disbursements, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285 as against Seagen; and

H. Daiichi Sankyo Japan be granted such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Daiichi Sankyo Japan demands a trial by jury of all issues triable in this action.

Dated: July 12, 2021

Respectfully submitted,

/s/ Preston K. Ratliff II

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of this document via electronic mail on July 12, 2021.

/s/ Preston K. Ratliff II